



TOP TEN VIOLATIONS IN THE BIOTECH/R&D INDUSTRY

Could they have been prevented?

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Objectives

- To make you aware of the most common violations
- To give you a refresher on the requirements
- To help you achieve compliance

Acronyms

| Acronym/Initials | Meaning |
|------------------|---|
| EPIC+ | Education, Process Improvements, Compliance for Environmental Risk Reduction <i>(formerly known as Environmental Protection Indicators for California)</i> |
| CUPA | Certified Unified Program Agency |
| CERS | California Environmental Reporting System |
| HMBP | Hazardous Materials Business Plan |
| EPA | Environmental Protection Agency |
| HSC | Health and Safety Code (California) |
| CCR | California Code of Regulations |
| MWMA | Medical Waste Management Act (California) |
| DTSC | California Department of Toxic Substances Control |
| RCRA | Resource Conservation and Recovery Act |

Trends in Violations cited

- Out of 2,430 inspections conducted at San Diego's Biotech and R&D facilities in the last three years

These are the top violations cited...

Top 10 violations

In Biotech and R&D facilities

July 2015 - July 2018

1. Inventory incomplete
2. HMBP not certified
3. No employee training
4. Failed to label HW
5. Inactive EPA/STATE ID
6. Failed to label MW
7. Site map not sufficient
8. HMBP not established
9. HMBP not submitted
10. CUPA permit not obtained

#1 Inventory

Chemical inventory
incomplete or not submitted
in CERS.

*HSC 25505(a)(1); 25507(a); 25508.1(a-b);
19 CCR 2654 (a) or (d)*



Inventory issues...

- *Not submitted*
- *Incomplete*
- *Not updated*
- *Type of inventory*
- *Incorrect physical characteristics*
- *Incorrect units*
- *Information missing*
 - Mixture components, Extremely Hazardous Substances, Waste codes, etc.

#1 Inventory

- Hazardous Materials (HM)
- Hazardous Wastes (HW)
- Medical Wastes (MW)



#1 Inventory – Hazardous Materials

HM Reportable Thresholds...

- ≥ 55 gal of liquid HM
- ≥ 500 lbs of solid HM
- ≥ 200 ft³ of gaseous HM

Lower HM Reportable Thresholds...

- Any amount of HW and MW generated
- \geq TPQ of EHS substances
- > 0 of highly toxic compressed gases with a TLV of 10 ppm
- ≥ 100 lbs of combustible metals/alloy
- > 0 pyrophoric/water reactive - metal or alloy (for example zinc powder/magnesium)

*HSC, Division 20, Chapter 6.95, Article 1, Section 25507
SDCC, Division 8, Chapter 11, Sections 68.1101-68.1120*

#1 Inventory – Hazardous Materials

Higher Reportable HM Thresholds...

- Inert gases
 - $\geq 1,000 \text{ ft}^3$ (sole health and physical hazard: asphyxiation hazard only and pressure release)
- Irritants/sensitizer
 - $\geq 5,000 \text{ lbs solids or } \geq 550 \text{ gal liquids}$ (sole hazard: irritant or a sensitizer)
- Refrigerant gases
 - $\geq 1,000 \text{ ft}^3$ non-flammable

#1 Inventory – Hazardous Materials

Higher Reportable HM Thresholds...

- Lubricating oil
 - *Report if volume of each type is > 55 gal OR the total volume for all types > 275 gal*
- Fluid in hydraulic systems
 - *Report if the combined storage capacity of petroleum products (including hydraulic oil) is $\geq 1,320$ gal*
- Oil-filled electrical equipment
 - *Report if the combined storage capacity of petroleum products (including oil from electrical equipment) is $\geq 1,320$ gal*

#1 Inventory – Medical Waste (MW)

- Report any MW generated at your facility regardless of the amount
 - Biohazardous waste
 - Pathology waste
 - Pharmaceutical waste
 - Trace chemotherapy waste
 - Waste generated in research pertaining to the production or testing of microbiologicals
 - Waste generated in research using human or animal pathogens
 - Sharps and laboratory waste
 - Waste generated in the cleanup of trauma scenes

*HSC, Division 104, Part 14
SDCC, Division 8, Chapter 9, Section 68.904; & Chapter 12*

#1 Inventory – Hazardous Waste (HW)

- Report any HW generated at your facility regardless of the amount
 - *A unique circumstance, one time only waste generation? For example, a one-time remodeling project that generates asbestos waste, do not report that inventory in CERS.*

Universal Waste (UW):

- A UW item is reportable when reaching HM thresholds at any one time within a year (55 gal, 500 lbs, 200 ft³)

#1 Inventory – Universal Waste

- Not fully regulated as HW
- Not to be put in trash
- Not to be treated
- Stored for no longer than one year
- Employee Training + records
- Labeling

| | |
|----------------------------|-------|
| UNIVERSAL WASTE | |
| SHIPPER | _____ |
| ADDRESS | _____ |
| CITY, STATE, ZIP | _____ |
| CONTENTS | _____ |
| _____ | |
| ACCUMULATION START DATE | _____ |

#1 Inventory – Universal Waste

Universal Waste –

- Batteries
- Mercury-containing equipment
- Lamp(s)
- Electronic Device(s)
- CRT(s)
- CRT glass
- Non-empty aerosol cans



#2 Annual HMBP Certification

HMBP not certified every 12 months as complete and accurate in CERS.

*HSC 25508(a)(1)(A), 25508.2;
19 CCR 2654(b)*

Facility Information

- Business Activities
- Business Owner/Operator Identification

Hazardous Materials Inventory

- Inventory
- Site Map

Emergency Response & Training Plans

- Emergency Response Plan
- Employee Training Plan
- Contingency Plan

#2 Annual HMBP Certification in CERS

- HMBP Certification → 3 CERS elements
- Has the HMBP been certified within the last 12 months?
- Check CERS submittal history
- Submit all 3 CERS elements together for easy tracking

| Home | Submittals | Facilities | Compliance |
|-----------------------------------|--|--|--|
| | <ul style="list-style-type: none">Start/EditHistoryArchive | | |
| Submitted | Facility | Inventory | Plans |
| 6/19/2018 9:35AM | Accepted 7/2/2018 | | |
| 3/29/2018 1:17PM | Accepted 5/11/2018 | Accepted 5/11/2018 | Not Accepted 5/11/2018 |
| 7/10/2017 8:45AM | Accepted 8/15/2017 | Accepted 8/21/2017 | |
| 4/13/2017 11:23AM | Accepted 4/13/2017 | Accepted 4/13/2017 | Accepted 4/13/2017 |
| 4/7/2017 1:07PM | Not Accepted 4/13/2017 | Not Accepted 4/13/2017 | |
| 3/3/2017 7:20AM | Not Accepted 4/13/2017 | Not Accepted 4/13/2017 | |
| 2/21/2017 8:40PM | Not Accepted 4/13/2017 | Not Accepted 4/13/2017 | |

#3 Employee Training

Initial &/or annual employee training not conducted in safety procedures for a hazardous material release or threatened release &/or employee training records not available or not maintained for 3 years.

HSC 25505(a)(4); 19 CCR 2659(b)



- *Initial training not provided*
- *Annual training not provided*
- *3-yrs worth of records not available*
- *No HMBP training provided*

#3 Employee Training



The Employee Training Program has to include, at a minimum:

- Methods for safe-handling of HM
- Procedures for coordination with local emergency response organizations
- Use of emergency response equipment
- All procedures required by the Emergency Response Plan (19 CCR 2658)
 - *Some of these requirements are: notification procedures (who, when, how, phone numbers, etc.); identification of local emergency medical assistance; mitigation, prevention, or abatement of hazards; evacuation; etc.*

CCR, Title 19, Division 2, Chapter 4, Article 4, Section 2659
HSC, Division 20, Chapter 6.95, Article 1, Section 25505

#3 Employee Training

The Employee Training Program must:

- Be reasonable and appropriate for the size of the business and the nature of the hazardous materials handled
- Address safety procedures in the event of a release or a threatened release of a HM or HW for all employees
- Take into consideration the responsibilities of the employees to be trained

*CCR, Title 19, Division 2, Chapter 4, Article 4, Section 2659
HSC, Division 20, Chapter 6.95, Article 1, Section 25505*



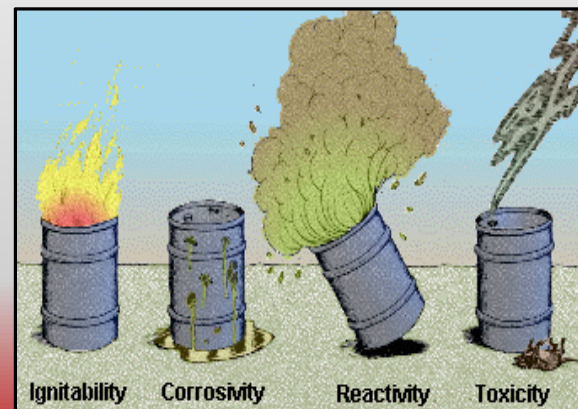
#4 HW Labeling

Failed to properly label/date hazardous waste container &/or tank.

22 CCR 66262.34(f)

HW Labeling issues...

- *Incomplete information*
- *Faded information*
- *Incorrect information*
- *No HW label*



#4 HW Labeling

Information required to be clearly marked and visible on each **container and tank (stationary)**:

- *Accumulation start date*
- *The words “Hazardous Waste”*

Additional information required on each **container and portable tank**:

- *Composition and physical state*
- *Hazardous properties*
- *Name and address of generator*

| HAZARDOUS WASTE | |
|---|--|
| STATE AND FEDERAL LAW PROHIBITS IMPROPER DISPOSAL IF FOUND, CONTACT THE NEAREST POLICE OR PUBLIC SAFETY AUTHORITY, OR THE U.S. ENVIRONMENTAL PROTECTION AGENCY OR THE CALIFORNIA DEPARTMENT OF TOXIC SUBSTANCES CONTROL. | |
| GENERATOR INFORMATION: | |
| NAME _____ | |
| ADDRESS _____ PHONE _____ | |
| CITY _____ STATE _____ ZIP _____ | |
| EPA ID NO. / | MANIFEST DOCUMENT NO. / |
| EPA WASTE NO. _____ | CA WASTE NO. _____ |
| ACCUMULATION START DATE _____ | |
| CONTENTS COMPOSITION: _____ | |
| PHYSICAL STATE: <input type="checkbox"/> SOLID <input type="checkbox"/> LIQUID | HAZARDOUS PROPERTIES: <input type="checkbox"/> FLAMMABLE <input type="checkbox"/> TOXIC <input type="checkbox"/> CORROSIVE <input type="checkbox"/> REACTIVITY <input type="checkbox"/> OTHER _____ |
| D.O.T. PROPER SHIPPING NAME AND UN OR NA NO. WITH PREFIX | |
| HANDLE WITH CARE! | |

#4 HW Labeling – Satellite Accumulation

Requirements for HW Satellite Accumulation

- Up to 55 gal of HW or up to 1 qt of Acutely HW or Extremely HW
- Accumulated only in containers
- Accumulated at or near the point of generation
(Satellite Accumulation Area = SAA)
- Has to be under the control of the operator of the process
(for example, in line of sight)
- Can't be accumulated onsite for over a year total
- Mark the initial date of waste accumulation
- Meet HW container requirements
(label, closed, good conditions, etc.)

CCR, Title 22, Division 4.5, Chapter 12, Article 3, Section 66262.34(e)

#4 HW Labeling – Satellite Accumulation

| HAZARDOUS WASTE SATELLITE ACCUMULATION | | |
|--|-------------|---------------------------------------|
| Generator Information: | | |
| NAME _____ | | |
| ADDRESS _____ | | |
| CITY _____ | STATE _____ | ZIP _____ |
| EPA ID# _____ | PHONE _____ | |
| COMPOSITION: (No abbreviations or chemical formulas) | | |
| _____ | _____ % | PHYSICAL FORM |
| _____ | _____ | <input type="checkbox"/> Solid |
| _____ | _____ | <input type="checkbox"/> Liquid |
| HAZARD CLASS | | |
| _____ | _____ | <input type="checkbox"/> Flammable |
| _____ | _____ | <input type="checkbox"/> Corrosive |
| _____ | _____ | <input type="checkbox"/> Toxic/Poison |
| _____ | _____ | <input type="checkbox"/> Reactive |
| SATELLITE ACCUMULATION START DATE: ____/____/____ | | |
| WASTE STORAGE ROOM START DATE: ____/____/____ Loc./Lab: _____ | | |

- Once the limit at the SAA has been reached (55 gal or 1 qt), do the following within 3 days:
 - Move container to central HW accumulation area, and
 - Mark the date when the satellite accumulation limit was reached (2nd date), and
 - Comply with accumulation time per the generator status, but never exceed 1 year total (from the initial accumulation start date)
- If the container does not get full within a year of satellite accumulation:
 - Arrange for disposal of the HW
 - Remember to never exceed 1 year

#5 EPA ID State ID

Failed to obtain &/or
maintain an active EPA ID
Number.

22 CCR 66262.12(a)

EPA ID issues...

- *EPA ID or State ID inactive*
- *EPA ID or State ID not obtained*
- *Incorrect ID obtained*

HW, Identification Number

<https://www.dtsc.ca.gov/IDManifest/PERMHWID.cfm>

EPA ID Number

≥ 100 Kg of RCRA HW/month
> 1 Kg of RCRA Acutely HW/month

CAR | CAP | CA | CAD | CAT

[Form EPA 8700-12](#)

State HW ID Number

< 100 Kg of RCRA HW/month
≤ 1 Kg of Acutely RCRA HW/month

Non-RCRA HW

CAL | CAC

[Form DTSC 1358](#)

HW e-Manifesting

<https://www.dtsc.ca.gov/IDManifest/Manifests.cfm>

What Generators Should Know

- Hazardous Waste Electronic Manifest Establishment Act on October 5, 2012
- e-Manifest launched nationwide on June 30, 2018
- Generators have the option to create and submit manifests electronically in e-Manifest. Generators may continue to use paper manifests after June 30, 2018; however, use of e-Manifest is encouraged by EPA.
- Existing 6-copy manifest form is being replaced with a new 5-copy form
- DTSC still collects manifests from waste generators and transporters
 - *Manifests received at TSD facilities will be downloaded from e-Manifest to DTSC HWTS in the future*

HW e-Manifesting

How Generators Can Be Impacted

- To use e-Manifest, generators will need
 - *To have an EPA or State Identification (ID) Number, and*
 - *To register at the EPA's e-Manifest system (<https://www.epa.gov/e-manifest>)*
- The e-Manifest system will only supply electronic copies of completed manifests to registered generators with e-Manifest accounts
 - *If no e-Manifest account, make arrangements with receiving facilities to obtain paper copies of completed/signed manifests (per recordkeeping requirements in 40 CFR part 262)*

HW e-Manifesting

What Generators Need to Know

- The e-Manifest system allows for three types of hazardous waste manifest creation options:
 - *Paper (generator, transporter, and receiving facility all sign on paper)*
 - *Hybrid (starts as paper manifest signed by the generator and then is signed electronically by the transporter and receiving facility)*
 - *Electronic (created in e-Manifest and electronically signed by all entities listed on the manifest)*
- Work with HW receiving facility to select manifest creation option

RCRAInfo

<https://rcrainfo.epa.gov/rcrainfoprod/action/secured/login>

The logo features the text "RCRA" in a bold, sans-serif font. The text is white and is set against a rectangular background that has a gradient from light gray on the left to dark red on the right.

Industry application of the online RCRAInfo webpage:

- **myRCRAid** – allows generators to electronically complete and submit EPA ID number Form 8700-12 to obtain/change an EPA ID Number.
- **RCRA Biennial Report** – will allow generators to electronically complete and submit EPA Form 8700-13A/B, the Hazardous Waste Report (Biennial Report).
- **e-Manifest** –will allow generators to electronically complete EPA Form 8700-22/22A (i.e...manifests) and submit/track their HW manifests online.

For assistance, email myRCRAid@dtsc.ca.gov

DTSC's HW ID Number eVQ Online System

<https://evq.dtsc.ca.gov/Home.aspx>



- Verify with the DTSC all HW ID number information annually –including federal EPA ID numbers (HSC 25205.16)
- DTSC Fees
 - *Annual ID # verification fee (for generators with ≥ 50 employees)*
 - *For each HW manifest (HSC 25205.15)*
- Failing to provide information to verify the accuracy of HW activity data can result in suspension of any and all ID #'s assigned and potential violations (HSC 25205.16)

*Access to the eVQ is limited by DTSC to the current eVQ cycle only.
Keep a copy of any DTSC invoice for your records.*

For assistance, email evq@dtsc.ca.gov

#6 MW Labeling

Primary containers accumulating MW not labeled with an electronic tracking system label or a label with generator's name, address, and phone number.

SDCC 68.1205

MW Labeling issues...

- *MW label missing*
- *Label on primary and/or secondary container*
- *Incomplete information*



#6 MW Labeling

- Primary containers' labels (i.e. red bags, sharps containers)
 - *Electronic tracking system or Label that includes:*
 - Generator's name
 - Generator's address
 - Generator's phone number
 - *Visible on the outside of the container*
 - *Attached to container when it is first used to accumulate MW*
- MW containers have to meet California MWMA criteria

#6 MW Labeling

- Biohazardous waste → red biohazard bag & labeled, “biohazardous waste” or biohazard symbol & “biohazard”
- Sharps waste → container USFDA approved & labeled, “sharps waste” or biohazard symbol & “biohazard”
- Trace chemotherapy waste → yellow bag, “chemotherapy waste”, “chemo”, on the lid and sides –visible from any direction
- Pathology waste → white bag, “pathology waste”, “path” on the lid and sides – visible from any direction
- Pharmaceutical waste → container USDOT and USDEA, “high heat” or “incineration only”, on the lid and sides –visible from any direction

#6 MW Labeling



Primary container? Secondary container?

#7 Site Map

Site map not submitted in
CERS or not sufficient.

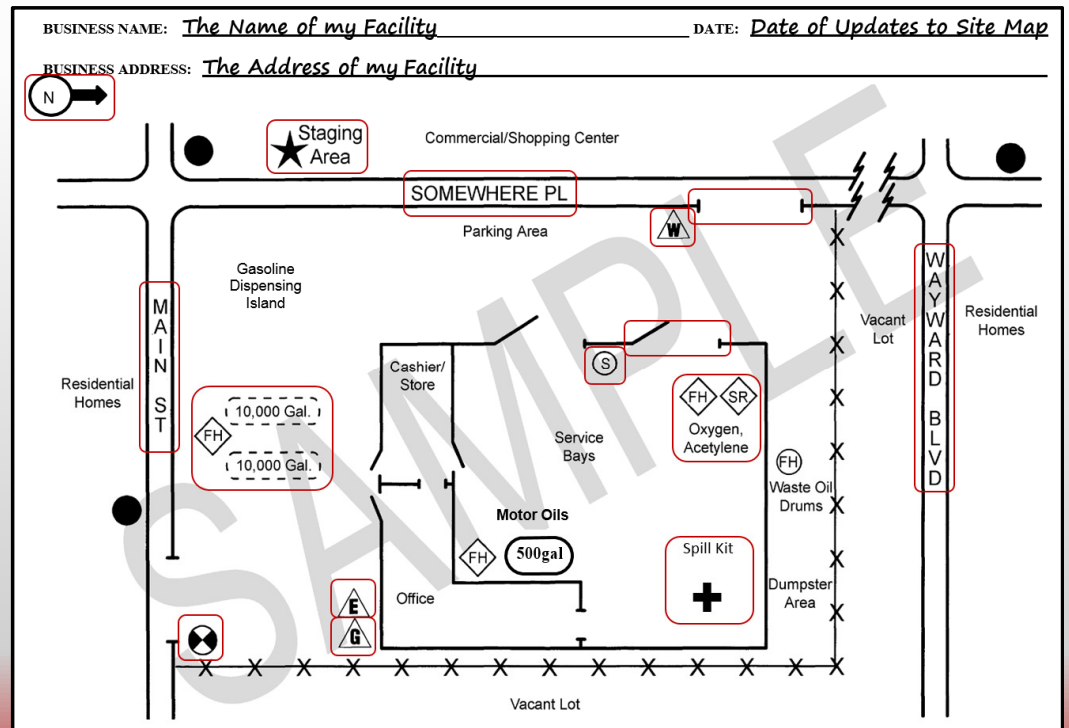
*HSC 25505(a)(2); 25508.1(f);
19 CCR 2652(a)(3)*

Site Map issues...

- *Not submitted*
- *Not updated*
- *Not enough information*
- *Too much or unnecessary information*
- *Multiple-page site map as multiple docs in CERS*
- *Obsolete site maps not deleted*

#7 Site Map

- North orientation
- Loading areas
- Internal roads
- Adjacent streets
- Storm and sewer drains
- Access and exit points
- Emergency shutoffs
- Evacuation staging areas
- HM handling and storage areas
- Emergency response equipment



#7 Site Map

What works well...

- Overview map
 - *Location, cross streets, neighboring facilities, entrances/exits, hydrants, storm drains, Knox box, utilities*
- Additional pages might be needed
 - *For buildings, for different floors, for areas that require more detail*
- Keep a digital version to facilitate updates
- Utilize the San Diego CUPA's site map template
 - *You can copy/paste all the required symbols*

#8 HMBP Not Established

Failed to establish and
implement an HMBP.

HSC 25505(a) and 25507(a)

A business plan shall contain all of the following information:

- *The chemical inventory*
 - information required by law and information necessary to protect the health and safety of persons, property, and the environment
- *A site map*
- *Emergency response plan*
- *Employee training plan*



#9 HMBP Not Submitted

HMBP not submitted to the CUPA in CERS.

*HSC 25508(a)(1)(A);
27 CCR 15188(a),(b),(d)*

Remember...

- HMBP has to be initially submitted to CUPA through CERS within 30 days of being subject to it
- Certify HMBP through CERS every 12 months
- Update HMBP through CERS within 30 days of any significant facility or operational changes
- If deficiencies in the HMBP, you will be notified by the CUPA through CERS. Resubmit revised HMBP within 30 days from the notice
- Submit required data fields and upload required documents (*PDF format preferred*) in CERS

#10 CUPA Permit Not Obtained

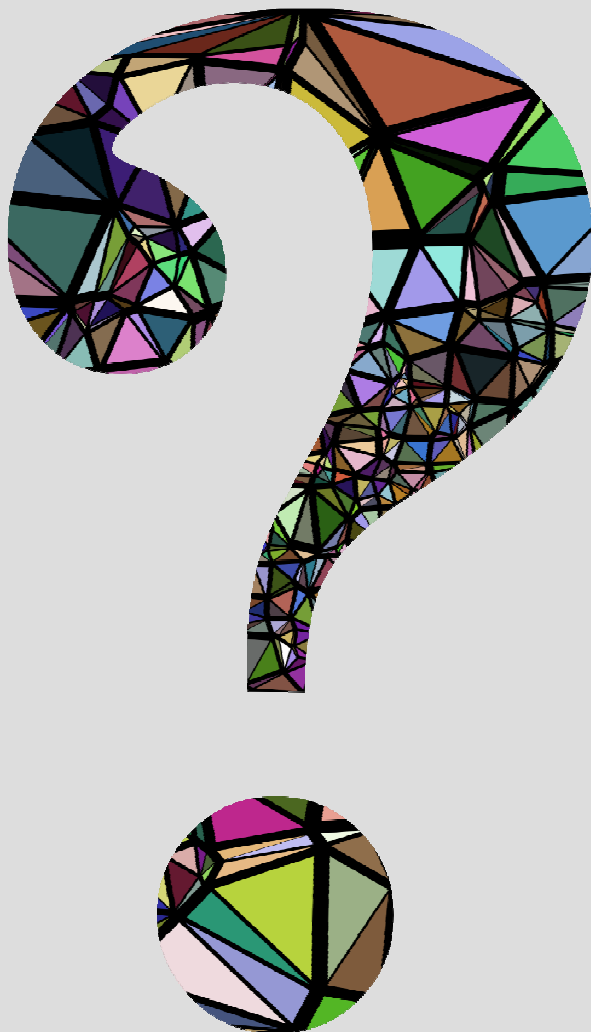
Unified Program Facility
permit not obtained.

SDCC 68.905; 68.906; 68.907



Facilities that require a CUPA permit:

- Those that are defined in the California Health and Safety Code, Division 20, Chapter 6.11
 - Aboveground Petroleum Storage Act (APSA) Program
 - California Accidental Release Prevention (CalARP) Program
 - Hazardous Materials Release Response Plans and Inventories (Business Plans)
 - Hazardous Waste Generator and Onsite Hazardous Waste Treatment (tiered permitting) Programs
 - Underground Storage Tank (UST) Program
- Those that generate, store, transfer, or dispose of medical waste



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